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Appl. No. 09/501,179

## Remarks

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Upon entry of the foregoing amendment, claims 1-21 and 23-28 are pending in the application, with claims, 19 and 21 being the independent claims. Claim 22 is sought to be canceled. New claims 27 and 28 are sought to be added. Support for these new claims may be found throughout the application and, in particular, in Example 1. Claims 1, 3, 6, 9, 19 and 21 are sought to be amended. Support for the amendments may be found throughout the application. In particular, support for the amendment to claim 3 may be found on page 12, lines 8-11. Support for the amendment to claim 9 may be found on page 14, lines 9-15. Support for the amendment to claim 21 may be found in canceled claim 22. The remaining amendments merely improve the clarity of the claims. These changes are believed to introduce no new matter, and their entry is respectfully requested.

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## Conclusion

Applicants respectfully submit that this application is now in condition for examination on the merits.

Respectfully submitted,

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## Version with markings to show changes made

## In the Claims:

Claim 22 has been canceled without prejudice or disclaimer.

Claims 1, 3, 6, 9, 19 and 21 have been amended as follows:

- 1. (Once amended) A method of classifying cancer cells in a body fluid sample of a patient with cancer or a patient suspected of having cancer, comprising: isolating circulating cancer cells in the body fluid sample of the patient, and characterizing said circulating cancer cells using cytological and morphological analyses by fluorescence microscopy to determine the classification of the cancer cells isolated, wherein the cancer cell classification comprises terminal cells[,] and proliferative cells[, and/or intermediate cells].
- 3. (Once amended) The method of claim 2, wherein said terminal cancer cell is about [10-50] 20-50 micrometers in diameter.
- 6. (Once amended) The method of claim 1, wherein at least one cancer cell is a terminal cancer cell with a nucleus[ and biological marker clusters within the cytoplasm].

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- 9. (Once amended) The method of claim 8, wherein said cancer cell is about [12-20] <u>25-35</u> micrometers in diameter.
- 19. (Once amended) A method of determining the presence or absence of [metastatic] cancer cells capable of causing metastatic cancer, comprising:
- (a) isolating circulating cancer cells in a body fluid sample of a patient
   with cancer or a patient suspected of having cancer;
- (b) characterizing said isolated cells using cytological and morphological analyses by fluorescence microscopy to distinguish cancer cell classes;
- (c) determining the classification of the cancer cells isolated, wherein the cancer cell classification comprises terminal cells[,] and proliferative cells[, and/or intermediate cells]; and
- (d) [assessing whether metastatic cancer is present or absent based on the classification determined in (c)] wherein when said cells are classified as proliferative cells, they are capable of causing metastatic cancer.
- 21. (Once amended) A method of determining the efficacy of a medical procedure, comprising:
- (a) conducting a first isolation of circulating cancer cells in a body fluid sample of a patient with cancer or a patient suspected of having cancer;
- (b) characterizing said isolated cells using cytological and morphological analyses by fluorescence microscopy to distinguish cancer cell classes;

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- (c) determining the classification of the cancer cells isolated, wherein the cancer cell classification comprises terminal cells[,] and proliferative cells[, and/or intermediate cells];
- (d) conducting a second isolation of circulating cancer cells in a bodyfluid sample of the patient;
  - (e) repeating (b) on the cells from the second isolation;
  - (f) repeating (c) on the cells from the second isolation; [and]
- (g) assessing whether a medical procedure is efficient based on the classification determined in (c) as compared to the classification determined in (f); and
- (h) wherein the first isolation is conducted before the administration
  of the medical procedure and the second isolation is conducted after the administration of
  the medical procedure.

New claims 27 and 28 have been added.